APR 4 2006

K051438

510(k) Summary of Safety & Effectiveness

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

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→ No longer there
~~Call Ed Canty x332~~
→ Trish Stephens

Date

June 1, 2005

Device

- Trade Name: Vanguard Reprocessed Compression Garments (Hill-Rom)
- Common Name: Compression Limb Sleeve, Compression Garment, SCD
- Classification: 21 CFR 870.5800
- Classification Name: Compressible Limb Sleeve
- Device Class: Class II
- Product Code: JOW

Predicate Devices

- Trade Name:
  - Hill-Rom ActiveCare™ DVT
    - → 510(k) number: K002287, K012994 [510(k) clearance received by Medical Compression Systems, Ltd.]
  - Vanguard Reprocessed Compression Garments
    - → 510(k) number: K012403

Indications for Use

When coupled with an appropriate inflation system, compression garments are intended to increase venous return from the legs and feet as a prophylaxis for the formation of deep vein thrombosis (DVT) or subsequent pulmonary embolism (PE) in high risk and/or non-ambulatory patients. The compression garments are prescription devices intended for a single patient use only.

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Contra-indications

Compression therapy is contraindicated in patients with:

- risk factors for pre-existing DVT or PE, including prolonged bed rest
- congestive heart failure and associated edema of legs, feet or lungs
- severe arteriosclerosis or other vascular ischemic disease
- localized skin conditions (dermatitis, vein ligation, gangrene, skin graft)
- acute stages of inflammatory phlebitis
- any condition where increased venous or lymphatic return is undesired.

Device Description

Compressible limb sleeves are devices that are used to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb and increasing venous flow. Compression therapy is generally prescribed as a prophylaxis for deep vein thrombosis (DVT). The compression system consists of two primary pieces: an air compression pump and a soft, flexible sleeve in which the patient's extremity is placed. A hose to the pump connects to the sleeve, and when the pump is turned on, the air inflates the sleeve, applying a gentle pressure to the patient's extremity.

Compression garments consist of a non-woven fabric with "hook and loop" fasteners for attaching around the leg. Air cells within the garment are molded to plastic hoses with connectors for attachment to the pump. The hoses and connectors are non-detachable and are reprocessed as part of the garment. Vanguard Reprocessed Compression Garments (Hill-Rom) contain multiple compartments and hoses that are sequentially pressurized.

Vanguard receives previously used compression garments from healthcare facilities; cleans, inspects, tests, repackages and sterilizes the garments; and returns them to a healthcare facility.

Technological Characteristics

The Vanguard reprocessed compression garments are essentially identical to the currently marketed OEM compression garments. No changes are made to the currently marketed devices' specifications (with the exception of sterility), and they possess the same technological characteristics. The OEM devices are marketed as non-sterile; Vanguard reprocessed compression garments are sterilized with ethylene oxide gas. Vanguard's sterilization validation demonstrates that sterility is achieved to a 10^{-6} assurance level.

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510(k) Summary of Safety & Effectiveness, Continued

Test Data

Cleaning, packaging, and sterilization validations, and performance and biocompatibility testing demonstrate that the reprocessed devices perform as intended and are safe and effective.

Conclusion

Based upon the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard Reprocessed Compression Devices are substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 4 2006

Vanguard Medical Concepts, Inc.
c/o Ms. Trish Stephens
Project Manager, Research and Development
5307 Great Oak Drive
Lakeland, FL 33815

Re: K051438
Vanguard Reprocessed Compression Garments (Hill-Rom)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: February 3, 2006
Received: February 6, 2006

Dear Ms. Stephens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051438

Device Name: Vanguard Reprocessed Compression Garments (Hill-Rom)

Indications for Use:

When coupled with an appropriate inflation system, compression garments are intended to increase venous return from the legs and feet as a prophylaxis for the formation of deep vein thrombosis (DVT) or subsequent pulmonary embolism (PE) in high risk and/or non-ambulatory patients.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Mechaber

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051438